UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PROCTER & GAMBLE COMPANY,	:	
Plaintiff,	:	**No. 07 Civ. 8379 (RJS)**
vs.	:	**ECF Case**
ULTREO, INC.,	:	
Defendant.	:	

SUPPLEMENTAL DECLARATION OF AARON BIESBROCK, D.M.D., PH.D. IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

Aaron Biesbrock, D.M.D., Ph.D., hereby says as follows:

1. I submit this supplemental declaration in support of P&G's Motion for Preliminary Injunction, and in particular to discuss how and why Ultreo's claims related to the efficacy of the Ultreo Ultrasound Toothbrush lack clinical support. In so doing, I will address the Ultreo's criticisms of the *in vivo* clinical study that P&G conducted and discussed in my initial affidavit. I also will address the clinical data that P&G has to substantiate certain advertising claims.

P&G'S CLINICAL STUDY OF ULTREO TOOTHBRUSH

2. Ultreo raises a number of criticisms of the clinical study P&G conducted of the Ultreo toothbrush. I will specifically address each of these criticisms in turn.

Use Of P&G Employees As Subjects

3. Ultreo first complains about the fact that I used "unblinded P&G employees" as subjects in this clinical study. (Opp'n Br. at 13). I disagree that the use of P&G employees as subjects in this clinical study has any impact on the validity of the results of the clinical study. Indeed, it is not uncommon for a company or university to use its employees as subjects in a clinical study. I understand that Ultreo used its employees in a number of its clinical tests.

4. Based upon the design of P&G's clinical study, the fact that the subjects were employees could not have biased the results. There were four treatment arms in P&G's clinical study. The first two arms involved the subjects brushing their teeth with the Ultreo toothbrush, either with the power on or the power off. The subjects brushed their teeth at the clinical site, while being monitored by the contract non-P&G clinic staff for compliance. The third arm of the study required a dental hygienist to hold the Ultreo toothbrush with the ultrasound waveguide three millimeters from the surface of the tooth, with the ultrasound feature engaged. In connection with the third arm, the subjects did not brush their teeth; in fact, the subjects did not touch the Ultreo toothbrush at all. The fourth arm required the subjects to swish with a toothpaste slurry. The subjects in this treatment arm were not even given a toothbrush, and, as with the other treatment arms, the subjects were observed by contract non-P&G clinic personnel for compliance.

5. Moreover, any suggestion that the P&G subjects were biased since a non-Oral B toothbrush was being tested is ludicrous. This is not a study where an Oral-B product is being compared with a competitor's product. The only toothbrush used in

this clinical study was the Ultreo toothbrush. The P&G subjects did not know the purpose of the study. The P&G subjects did not know whether this was a toothbrush that P&G was considering licensing or acquiring. Indeed, P&G routinely conducts tests on products that it is considering licensing or acquiring.

6. The subjects for this clinical study were selected from a pool of P&G subjects that had participated in an earlier clinical study. Subjects were selected to participate in this clinical study based upon their demonstrated ability to follow instructions given to them and their reliability in attending scheduled visits. Subjects from this pool also participated in three other clinical studies between the initial screening study and the Ultreo study. Exhibit 1 contains a chart showing the list of subjects in the general pool, identified by number. Exhibit 1 also discloses in which studies these subjects participated.

7. In order to rebut any suggestion that these subjects were biased in favor of P&G, I conducted a number of analyses regarding these subjects.

8. First, I considered whether there was any evidence that the subjects that were selected to participate in brushing studies from the larger pool of subjects were not representative of the entire pool. Based upon my analysis, it is clear that the subjects used in P&G's clinical study were representative of the subjects found in the general pool. This conclusion is based upon a consideration of the results of the examiner screening that was done (Study No. 2006126). The results from the examiner screen of the entire pool (n=94) and the examiner screen of those subjects selected to participate in P&G's ensuing toothbrush clinical studies (n=64) reveal that they were representative. Exhibit 2 is a graphical representation of these results.

9. Second, I considered whether there was any evidence that these subjects tended to favor Oral-B products in the subsequent studies in which they participated. I found that Oral-B products often performed worse than competitors' products in two of the three subsequent studies. For example, in one subsequent study, two Oral-B toothbrushes – the Old Pulsar and New Pulsar – did not perform as well as both a manual toothbrush and a competitor's toothbrush. Exhibit 3 is a graphical representation of the results from Study No. 2007022. Similarly, in another subsequent study using subjects drawn from this same pool, both the current Vitality Sonic toothbrush made by Oral-B and an experimental new Vitality Sonic toothbrush made by Oral-B performed less effectively than a manual toothbrush.[1] Exhibit 4 is a graphical representation of the results from Study No. 2007070.

10. These observations eliminate any suggestion that these subjects were biased in favor of P&G and influenced the study results because of that bias.

Measurement Of The Contribution Of The Ultrasound Feature

11. Ultreo also complains that the clinical study P&G conducted does not "demonstrate anything about the contribution of *ultrasound* to the Ultreo's plaque removal capabilities." (Opp'n Br. at 13 (emphasis in original); McInnes Decl. ¶ 48; Berg Decl. ¶ 36). Apparently, Ultreo fails to comprehend how this clinical study isolates and measures the clinical effect of the ultrasound feature of the Ultreo toothbrush. The measurement taken when the hygienist holds the Ultreo toothbrush with the ultrasound

[1] I also compared the results of Study No. 2007070 with an external, clinical study that also compared the Oral-B Vitality Sonic toothbrush with a manual toothbrush. In that external study, the manual toothbrush also outperformed the Oral-B Vitality Sonic Toothbrush. However, the magnitude of the performance benefit for the manual toothbrush over the Oral-B Vitality Sonic was actually smaller in the external study than the internal P&G study. Exhibit 5 is a graphical representation of these results.

waveguide three millimeters from the surface of the teeth is the measurement that isolates the ultrasound from any bristle action and would thereby demonstrate any cleaning effect of the ultrasound feature of the Ultreo toothbrush. The swishing of the toothpaste slurry without using any toothbrush at all is the negative control. In addition, the comparison of the Ultreo turned on and used per manufacturer's instructions compared to the Ultreo turned off and used like a manual toothbrush is an alternative approach to measure the presence of a beyond the bristles cleaning effect.

12. Ultreo describes this hygienist administered treatment arm as a "bizarre protocol" "that was obviously created to achieve the results and litigation ends that P&G desired." (Opp'n Br. at 13). That simply is not true. Instead, this treatment arm was selected in an effort to replicate the results of Ultreo's *in vitro* study where the waveguide of the Ultreo toothbrush was held three millimeters from the surface of hydroxyapetite discs.

13. Dr. McInnes argues that since the dental hygienist held the Ultreo toothbrush stationary in certain spots in the mouth, "the waveguide tip never came close to the majority of teeth." (McInnes Decl. ¶ 49). Dr. McInnes recognizes, though, that the instructions would mean that the dental hygienist held the Ultreo toothbrush in ten different locations on each of the bottom and upper jaws with the head of the toothbrush covering ~3 teeth at each location for 6 seconds. Since the dental hygienist held the Ultreo toothbrush in ten locations in each jaw and the fact that – on average – a person has 14 teeth on each jaw, this means that the ultrasound waveguide would be held close to nearly every tooth.

Adequate Fluid In The Mouth

14. Dr. McInnes also argues that there would not be sufficient fluid near the ultrasound waveguide while the dental hygienist held it "to allow the ultrasound to work." (McInnes Decl. ¶ 50; *see also* Berg Decl. ¶ 36). Dr. McInnes fails to appreciate that simply placing a toothbrush or toothpaste, even without brushing, in a subject's mouth will stimulate saliva flow. A slurry of toothpaste, saliva and foam was created requiring the subjects to expectorate at the end of the 2 minute treatment. Dr. Berg and Dr. McInnes have both argued that stimulated salivary flow will result in 4-6 ml of saliva over a 2 minute period.

15. Furthermore, I wanted to evaluate whether the difference between the amount of fluid seen around the upper and lower teeth manifested itself as any difference in the efficacy of the ultrasound feature. Due to the forces of gravity, more fluid will collect in the lower jaw around the lower teeth. Consequently, I analyzed the difference between the plaque removed on the maxillary (upper) and mandibular (lower) arches by holding the ultrasound waveguide three millimeters from the tooth surface. There was no statistical difference between the two measurements.

P&G's Clinical Study Is Not Inconsistent With Other Clinical Research

16. Dr. McInnes also argues that P&G's clinical study is inconsistent with Ultreo's clinical data that shows the Ultreo toothbrush outperforms a manual brush in both overall and interproximal plaque measurements. (McInnes Decl. ¶ 52). The P&G study does not compare the Ultreo to a manual brush, but rather against the Ultreo brush itself without ultrasound in order to isolate any incremental plaque cleaning benefit provided by the ultrasound. The comparison of P&G's clinical study to Ultreo's own

clinical data does not reveal any inconsistency since Ultreo does not have any reported clinical data regarding the effectiveness of the ultrasound feature. In none of the clinical studies disclosed to P&G is there any analysis related to the effectiveness of the ultrasound feature.[2]

17. Dr. McInnes testified that the clinical data he is referring to comes from the Baltuck and Goyal studies. However, as discussed in my Expert Report submitted on November 27, 2007, the results of the Baltuck study are unreliable. Moreover, the Goyal study was a study to measure gingivitis; overall plaque scores were not taken in connection with the primary objective of the study.[3] Even assuming that it is appropriate to consider the plaque results of the Goyal study, Ultreo removed a comparable amount of plaque to a manual brush at nearly every endpoint. The only statistically significant difference in plaque removal arose in connection with overall plaque measurements taken at the second visit. (McInnes Decl. ¶ 14).

18. Both Dr. McInnes and Dr. Berg highlight the fact that as a general matter power toothbrushes perform better than manual toothbrushes and suggest that the fact that the Ultreo toothbrush with the power off performed better than the Ultreo toothbrush with the power on demonstrates that P&G's clinical study is flawed. (McInnes Decl. ¶ 57; Berg Decl. ¶ 38). However, comprehensive evidence based meta-analyses of power toothbrush comparisons to manual toothbrushes by an independent

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[2] Ultreo did collect data in the Baltuck study regarding the performance of the Ultreo toothbrush with the ultrasound function disengaged. However, Ultreo never conducted any analysis of that data.

[3] This analysis of the Goyal study is hindered by the fact that I have not seen the protocol or final report for this study. My conclusions are based upon the abstract available on the Ultreo website and the comments made by Dr. McInnes in his declaration and deposition regarding this study.

academic consortium has concluded that the clinical evidence supports that only rotation-oscillation power toothbrushes have been proven to be superior to manual toothbrushes. A copy of the Cochrane review was attached to my initial declaration as Exhibit K. The evidence for other types of power toothbrushes is lacking at this time. None of the studies referenced by Dr. Berg and Dr. McInnes, though, involve tests on the Ultreo toothbrush. There may be unique aspects of the Ultreo toothbrush, such as the fewer number of bristles on the brushhead, that could influence these results. Additionally, the difference in brushing instructions between the two treatment groups could explain the results. The instructions for the Ultreo toothbrush direct the user to hold the brush lightly and move it in a small circular fashion; whereas a subject using the Ultreo toothbrush without any power and as a manual toothbrush could involve more aggressive bristle action.

ULTREO'S *IN VITRO* STUDY DOES NOT MIMIC ACTUAL CONDITIONS IN THE MOUTH

19. In my initial affidavit in support of P&G's Motion for Preliminary Injunction, I identify a number of differences between the *in vitro* study conducted by Ultreo and the actual conditions of the mouth. These differences were based upon my review of the abstract of the Ultreo *in vitro* study available on the Ultreo website.

20. In Dr. McInnes' declaration, he discloses for the first time that Ultreo's *in vitro* study utilizes hydroxyapitate discs pretreated with gastric mucin. (McInnes Decl. ¶ 39). However, rinsing the hydroxyapitate discs with gastric mucin does not make the Ultreo *in vitro* study begin to approach the actual conditions in the human mouth. Gastric mucin, which is found in the stomach, is a large molecular weight glycoprotein, and is substantially different relative to human salivary mucins found in

saliva. More important, saliva contains numerous proteins and glycoproteins (histatins, statherin, sIgA, MG1, MG2, amylase, PRPs, cystatins, etc.) that have been shown to play a role in bacterial attachment to tooth surfaces. Dr. McInnes recognizes that saliva contributes to the ability of bacteria to adhere to the surface. In short, gastric mucin is not saliva, nor does it adequately replace the functionality of saliva. Additionally, gastric mucin is typically acquired commercially from non-human sources (cow or pig) and it is recognized that there are structural and functional differences in mucins that are species specific. I understand that Ultreo does not know the source of the gastric mucin that was used. Finally, the use of gastric mucin is unusual since saliva is easily collected.

P&G'S ADVERTISING CLAIMS

21. Ultreo argues throughout its papers that P&G relies solely on laboratory studies to make certain advertising claims. However, while P&G may refer to laboratory studies in its advertising, in each instance in which it does, P&G also has clinical data to substantiate the advertising claim.

Crest Pro-Health Rinse

22. Ultreo has highlighted P&G's advertisement for Crest Pro-Health Rinse "kills 99% of common germs that can cause plaque, gingivitis and bad breath" and argues that this advertisement is based solely upon laboratory studies. (Opp'n Br. at 10). In fact, P&G has both *in vitro* and *in vivo* data that support this advertising claim.

23. In 2004, P&G conducted an *in vitro* test of Crest Pro-Health rinse to see how long it would take to kill a battery of microorganisms well accepted to be representative of the organisms associated with gingivitis. The faster the microorganisms were killed, the more effective the product is at killing germs. The results of this study

showed that 99% of the microorganisms tested were killed after 30 seconds. Attached as Exhibit 6 is a copy of the study results for Study No. OC 0001 2004.

24. Also in 2004, P&G conducted another *in vitro* test of Crest Pro Health Rinse. This test measured Minimum Inhibitory Dilution and Minimum Bactericidal Dilution, which measures the amount of concentration required to kill the microorganisms. The lower the concentration required, the more effective the product. Again, Crest Pro-Health Rinse was tested against a battery of organisms well accepted to be representative of the organisms associated with plaque and gingivitis. Water was used as the control. The test showed that Crest Pro Health Rinse has good hostility against organisms implicated in plaque and gingivitis. Attached as Exhibit 7 is a copy of the study results for Study No. OC 0002 2004.

25. P&G also conducted an *in vivo* test in 2004 of Crest Pro-Health Rinse. The subjects participated in a randomized, two-period, crossover study. Crest Pro-Health Rinse was tested against water. The subjects gave saliva, then rinsed with either Crest Pro-Health Rinse or water and then gave additional saliva. Colony Forming Units ("CFUs") of bacteria were measured in the saliva samples and the results demonstrated that Crest Pro-Health Rinse killed 99% of salivary microbes. Attached as Exhibit 8 is a copy of the study results for Study No. OC 0020 2004.

26. Ultreo further argues that P&G makes advertising claims regarding the bacteria-reducing potential of an entire product based solely on laboratory studies. (Berg Decl. ¶11). This is false. The short-term and long-term bacteria reducing benefit of Crest Pro-Health Rinse has been clinically demonstrated. For example, Crest Pro-Health was shown to provide significant reductions in plaque bacteria and gingivitis at

six months. Attached as Exhibit 9 is a copy of the Mankodi at al. article as published in the American Journal of Dentistry in 2005.

Vicks Early Defense Foaming Hand Sanitizer

27. Ultreo also points to P&G's advertisement for Vicks Early Defense Foaming Hand Sanitizer as additional evidence that P&G relies only upon laboratory studies for certain claims. Ultreo has identified an advertisement for Vicks Early Defense Foaming Hand Sanitizer that claims it "Kills 99% of germs. Helps fight germs for up to 3 hours.*" A disclosure is found at the bottom of the advertisement that says *under laboratory conditions." Again, Ultreo is wrong that P&G lacks clinical support for this claim. Instead, P&G relies upon a number of *in vitro* and *in vivo* studies for this claim.

28. P&G conducted an *in vivo* study called "Efficacy of Hand Sanitizer in a Modified Health Care Personnel Handwash Study." This study showed a statistically significant reduction of bacteria on the subjects' hands that participated in this study, including a 99% reduction of E. coli on human hands. Attached as Exhibit 10 is a copy of the study results for Study No. 2006082.

29. P&G also conducted a clinical test that measured viruses found on the fingerpads of human subjects. The subjects were treated with Vicks Early Defense Hand Sanitizer and then inoculated with rhinovirus. Viral titer level measurements were taken at 15 minutes, 1, 2 and 3 hours. Vicks Early Defense was statistically significantly better than placebo after 15 minutes, 1, 2 and 3 hours at making rhinovirus inactive. Attached as Exhibit 11 is a copy of the study results for Study No. 2006090.

30. P&G also conducted a clinical test that measured the ability of Vicks Early Defense to kill *E. coli* bacteria. The subjects were treated with Vicks Early

Defense Hand Sanitizer and then inoculated with *E. coli* bacteria. CFU measurements were taken at 1, 2 and 3 hours. The reduction of bacteria by Vicks Early Defense was statistically significantly higher than placebo after 1, 2 and 3 hours. Attached as Exhibit 12 is a copy of the study results for Study No. 2006083.

31. P&G conducted an *in vitro* test that measured the Minimum Inhibitory Concentration of Vicks Early Defense and demonstrated that Vicks Early Defense was effective at killing 13 microorganisms. Attached as Exhibit 13 is a copy of the study results for Study No. NB00012006.

32. P&G conducted an *in vitro* Time Kill Study to measure the length of time that it took Vicks Early Defense to kill two microorganisms – *E. coli* and *S. aureus*. Vicks Early Defense killed 99% of approximately 22 different types of germs, including *E. coli* and *S. aureus*. Attached as Exhibit 14 is a copy of the study results for Study No. NB00022007.

33. P&G conducted an *in vitro* Bacterial Residual Effectiveness Test. This study demonstrated a reduction in the bacteria *S. epidermidis* and *E. coli* compared to ethanol control. After both 1 and 3 hours, Vicks Early Defense completely eliminated *S. epidermidis*. Residual efficacy of Vicks Early Defense was shown against *E. Coli* after 1 and 3 hours. Attached as Exhibit 15 is a copy of the study results for Study No. NB00042006.

34. P&G also conducted an *in vitro* Viral Residual Effectiveness Test. This study demonstrated a reduction in rhinovirus after 3 hours compared to ethanol control. Vicks Early Defense reduced the level of the virus to the detectable limit. Attached as Exhibit 16 is a copy of the study results for Study No. NB0032006.

OxyJet Oral Irrigator

35. Ultreo also argues that P&G does not have any clinical support for its claim that the Oxyjet oral irrigator "mixes air and water, then pressurizes it to form millions of long-lasting micro-bubbles designed to attack plaque bacteria." (Opp'n Br. at 11). Again, Ultreo has no support for its argument because P&G has both *in vitro* and *in vivo* studies that support this claim.

36. In a recent *in vivo* study, the use of mouthrinse was compared to water in the Oxyjet Oral Irrigator. There was a significant reduction of interproximal plaque bacteria versus baseline with water in the Oxyjet Oral Irrigator. Attached as Exhibit 17 is a copy of the study results for Study No. 2007063.

37. In another *in vivo* study, the Oxyjet Oral Irrigator inhibited experimentally induced gingivitis (where the probe induced bleeding) significantly better than a traditional irrigator (that dispersed water without "microbubbles"). This test employed a split-jaw method where each subject has each treatment on either side of his or her mouth. The study design allows for a sort of simultaneous crossover design, where subjects themselves serve as controls. Attached as Exhibit 18 is a copy of the Jepsen study results.

38. In an *in vitro* test, the Oxyjet Oral Irrigator was tested against the earlier version of the irrigator to see if it hindered the growth of the bacteria on denture plastic. The test revealed that the Oxyjet Oral Irrigator was more effective than the prior irrigator at hindering the growth of the bacteria. Attached as Exhibit 19 is a copy of the Jena study results.

39. In an *in vivo* study, the Oxyjet Oral Irrigator used together with tooth brushing was shown to significantly reduce gingival bleeding at 8 weeks. In this study, a control group brushed with a manual toothbrush only. At 4 weeks the Oxyjet Irrigator with manual toothbrush users had significantly reduced gingival bleeding compared to users of manual toothbrushes alone. Attached as Exhibit 20 is a copy of the Frascella Study.

Plaque Removal by Pulsating Feature

40. Ultreo also argues that P&G does not have any clinical support for its claim that the pulsating feature of certain of its power toothbrushes enhances the plaque-removal capabilities of the toothbrush. (Opp'n Br. at 11). Again, P&G has clinical support demonstrating the effectiveness of its pulsating feature of certain of its toothbrushes.

41. In a clinical study, subjects brushed with either a traditional oscillating toothbrush or one that oscillated and pulsed. After 2 minutes of brushing, those who used the combination pulsating and oscillating brush removed statistically more plaque both overall and in interproximal areas as compared to the oscillation only brush. Attached as Exhibit 21 is a copy of the Ernst study results as published in the American Journal of Dentistry in 1998 and an abstract of this study as found on the Oral-B website.

42. Additionally, a review article written by Dr. Paul Warren highlights the results of both *in vitro* and *in vivo* tests that show that the Oral B pulsating toothbrush performs significantly better than other power toothbrushes. Attached as Exhibit 22 is a copy of the article written by Dr. Warren.

Crest Extra White plus Scope Toothpaste

43. Ultreo also complains that P&G does not have clinical studies to support its advertising that Crest Extra White plus Scope Toothpaste "combines Scope freshness with extra whitening power* vs. Crest Whitening plus Scope in lab tests." (Opp'n Br. at 10). Again, P&G has clinical and laboratory studies to support this advertising claim.

44. Crest Extra White plus Scope toothpaste is similar to the original Crest Whitening plus Scope toothpaste. Both products contain 3.3% pyrophosphate, a clinically proven anti-tartar agent. The difference between the two products is that Crest Extra White plus Scope contains more silica than Crest Whitening plus Scope.

45. Clinical studies show that higher levels of silica provide better stain removal and prevention. For example, one *in vivo* study conducted by P&G demonstrated that toothpaste containing more silica was significantly better at removing stains than other toothpaste. Attached as Exhibit 23 is a copy of Study No. 1995056.

46. The results of *in vitro* Pellicle Cleaning Ratio ("PCR") studies rank the cleaning or polishing ability of toothpaste formulas and such results have been shown to correlate to comparative clinical whitening outcomes. Attached as Exhibit 24 is a copy of the Stooky et al. article as published in the American Journal of Dentistry in 1982.

47. For example, Crest Extra Whitening toothpaste has been clinically shown to provide an extra whitening benefit over Crest Cavity Protection. These clinical results are consistent with prior PCR tests that accurately predicted that Crest Extra Whitening would provide significantly better surface stain removal than Crest Cavity

Protection based on a superior PCR score. Attached as Exhibits 25 and 26 are copies of Study Nos. 1997065 and 1997071.

48. PCR tests measure and predict the ability of toothpaste to remove stained pellicle and therefore extrinsic stains from enamel. The degree of stained pellicle removed is largely a function of the abrasivity of the toothpaste which depends on how much silica is included in the toothpaste formula. A PCR test comparing Crest Extra White Plus Scope shows better PCR results than Crest Whitening plus Scope. Attached as Exhibit 27 is a copy of Study No. 061014.

49. Another *in vitro* test, Radioactive Dentin Abrasion ("RDA"), is the most commonly used and most widely accepted method of measuring toothpaste abrasivity. RDA tests have also been clinically validated. Crest Extra White Paste plus Scope is statistically significantly better than Crest Extra Whitening and Crest Whitening Plus Scope in its RDA score, meaning that it is more abrasive due to its higher level of silica and will polish away more stain from the teeth. Attached as Exhibit 28 is a copy of Study No. 06-152.

INTELLICLEAN

50. Ultreo also argues that P&G made advertising claims that the Intelliclean system could clean "beyond the bristles" in October 2004 based solely on laboratory studies. (Opp'n Br. at 2, 5; McInnes Decl. ¶¶ 24-30; Berg Decl. ¶ 21). Ultreo overlooks the published clinical data supporting the ability of the Intelliclean system, which includes the brush and an integrated toothpaste which was ejected through the head of the toothbrush during brushing, to clean beyond the reach of the bristles.

51. The Intelliclean system was a joint venture between P&G and Philips, where a special formulation of Crest toothpaste is placed within the handle of a Sonicare toothbrush and the toothpaste is continuously dispensed from the brush during use. This power toothbrush is distinct from all Sonicare and other power toothbrushes on the market in that toothpaste is actually propelled from the brush head. When P&G acquired Gillette and the Oral B brand of power toothbrushes, it was required to divest Intelliclean.

52. At the time that P&G was marketing the Intelliclean product with Philips, P&G and Philips divided responsibility for studies and claims. P&G was responsible for studies and claims related to the special formulation of Crest toothpaste. Philips was responsible for studies and claims related to the Sonicare brush.

53. With regard to the "beyond the bristles" claims, there is a clinical study that demonstrates the Intelliclean system was able to clean beyond the reach of the bristles. Because the toothpaste is actually being ejected from the head of the toothbrush, it gives it the unique ability to reach beyond the bristles. In a clinical study done by Ashley P. Barlow, *et al.*, entitled "Pharmacodynamic and Pharmacokinetic Effects in Gingival Crevicular Fluid From Re-dosing During Brushing," it was shown that the Intelliclean product led to a significantly increased cleaning effect beyond the reach of the bristles, as seen in significantly greater reduction in bacterial count in gingival crevicular fluid[4] and higher levels of surfactant (the active cleaning ingredient in toothpaste) in gingival crevicular fluid up to two hours after brushing as compared to the same brush with regular bolus dosing of toothpaste (rather than the integrated Intelliclean

[4] Gingival crevicular fluid is generally recognized as a key source to study environmental factors associated with periodontal disease.

brush employing in-mouth redosing). Gingival crevicular fluid is found below the gumline, beyond the reach of the bristles. A copy of the results of this study, as reported in the Compendium of Continuing Education in Dentistry, is attached as Exhibit 29.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 12th day of December, 2007.

Aaron Biesbrock, D.M.D., Ph.D.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing was served electronically by the Court's ECF system pursuant to the rules of this court.

Dated December 12, 2007

s/ Laura W. Sawyer
Laura W. Sawyer